



PATENT
1173-485P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Mary R. FLACK et al.

Serial No.: 08/379,872

Group: 1205

Filed: January 27, 1995

Examiner: Unassigned

For: GOSSYPOL FOR THE TREATMENT OF CANCER

37 CFR § 1.132 DECLARATION

Honorable Commissioner of Patents
and Trademarks
Washington, DC 20231

Sir:

I, Marcus M. Reidenberg, MD, FACP, declare as follows.

1. I am a Professor of Pharmacology and Medicine at Cornell University Medical College, New York, NY., and I am a co-inventor of the subject matter disclosed and claimed in the above-identified application, as well as in its parent U.S. Patent Application (Serial No. 07/551,353, filed on July 12, 1990), now U.S. Patent No. 5,385,936, issued on January 31, 1995. I am also an expert in the field of the present invention, and particularly I am an expert on the antineoplastic properties of gossypol, its anti-cancer effective metabolites and its physiologically acceptable salts. My Curriculum Vitae is attached to the present declaration as evidence that I am an expert of the type asserted.

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3. In support of my declarations concerning gossypol and gossypol acetic acid as set forth in paragraphs 4 and 5 below, I rely on (i) my scientific expertise in the field of the field of the claimed invention, (ii) my familiarity with the metabolism of gossypol and gossypol acetic acid, (iii) my familiarity with relevant literature in the present art field, including the following reference, which is attached to this declaration.

Roger Adams and T.A. Geissman, "Gossypol, A Pigment of Cotton Seed", Chem. Rev. 60:555-574 (1960).

And, in support of my declarations concerning gossypol and gossypol acetic acid set forth in paragraphs 4 and 5 below, I also rely upon an attached copy of a 37 CFR 1.132 declaration of Mary R. Flack dated February 12, 1992 (with accompanying documents referred to therein), which was filed on April 8, 1992, in the matter of the parent U.S. Patent Application Serial No. 07/551,353.

4. Gossypol acetic acid is a loosely bound complex of gossypol with acetic acid. The acetic acid can be removed by simply allowing an ether solution of gossypol acetic acid to evaporate in contact with an aqueous layer. The acetic acid can also be removed in the laboratory by steam distillation in a vacuum. Other analogous complexes of gossypol have been formed with formic, propionic and butyric acids. The loose complexes that gossypol forms with these analogous organic acids are not a single molecule or a salt of gossypol, but are loose complexes. None of

the organic acids that have been complexed with gossypol, when tested by themselves, have antineoplastic activity.

5. The loose complex of gossypol with acetic acid is easily dissociated into its component parts of gossypol and acetic acid. Gossypol acetic acid, *in vivo*, dissolves in the lipids of the body, the body lipids being in contact with an aqueous phase (i.e., the extracellular and intracellular fluid). Body lipids thus permit dissolution of the acetic acid from the gossypol moiety, with the released acetic acid from the complex likely being metabolized by the body rather than just evaporating as occurs in a laboratory setting. For these reasons, it follows that it is the gossypol moiety itself that is responsible for the antineoplastic activity that has been observed and demonstrated in the present inventor's studies (e.g., those set forth in the accompanying copy of the earlier filed 37 CFR 1.132 Declaration of Mary R. Flack (who is one of the present inventors)). Thus, it is both reasonable and scientifically prudent to assume that gossypol complexed with any organic anion would have the same antineoplastic effects as gossypol complexed with acetic acid.

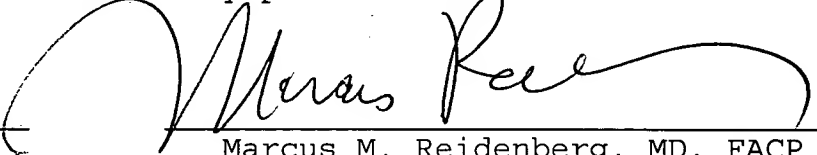
Marcus Reider

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6. I hereby declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patents issued therefrom.

9/21/95

Date



Marcus M. Reidenberg, MD, FACP

CURRICULUM VITA

Marcus Milton Reidenberg

Born: Philadelphia, Pennsylvania
January 3, 1934

Married: 1957

CURRENT POSITIONS

Cornell University Medical College
New York, NY

Professor of Pharmacology
Professor of Medicine and Head,
Division of Clinical Pharmacology
Assistant Dean, Departmental
Associates Program

The New York Hospital
New York, NY

Attending Physician

Rockefeller University
New York, NY

Visiting Physician

PREVIOUS POSITIONS

Cornell University Medical College
New York, New York

1981-1982, Acting Associate Dean

1976-1980, Professor of
Pharmacology/Associate Professor
of Medicine, and Head,
Division of Clinical Pharmacology

The New York Hospital
New York, New York

1975-1980, Associate Attending
Physician

Rockefeller University
New York, New York

1975-1977, Visiting Associate
Physician

Cornell University Medical College
New York, New York

1975-1976, Associate Professor of
Pharmacology/Associate Professor
of Medicine

Temple University
Philadelphia, Pennsylvania

1972-1974, Associate Professor of
Pharmacology/Associate Professor
of Medicine and Head, Section of
Clinical Pharmacology

Temple University
Philadelphia, Pennsylvania

1971-1972, Associate Professor of
Pharmacology/Assistant Professor
of Medicine and Head, Section of
Clinical Pharmacology

SOCIETY MEMBERSHIP

Association of American Physicians	Sigma Xi
American Society for Clinical Investigation	The Harvey Society
American College of Physicians (Fellow)	The New York Academy of Sciences
Society for Experimental Biology and Medicine	The American Society of Nephrology
American Society for Pharmacology and Experimental Therapeutics	American Association for the Advancement of Science
American Society of Tropical Medicine and Hygiene	Council on Basic Science, American Heart Association
American Society for Clinical Pharmacology and Therapeutics	Royal Society of Tropical Medicine and Hygiene
American Federation for Clinical Research	Royal Society of Medicine (Fellow)
International Association for the Study of Pain	American Geriatrics Society

LICENSES AND CERTIFICATIONS AND AWARDS

License to Practice Medicine in Pennsylvania and New York.

Certified by American Board of Internal Medicine, December 7, 1967.

Fred Conrad Koch Travel Fellow of The Endocrine Society Award, 1968.

Research Career Development Award, National Institute of General Medical Sciences, National Institutes of Health, 1970-1974.

Temple University S.A.M.A. Teacher Recognition ("Golden Apple") Award, 1973.

Rawls-Palmer Award of the American Society for Clinical Pharmacology and Therapeutics, 1981.

Experimental Therapeutics Award of the American Society for Pharmacology and Experimental Therapeutics, 1983.

William Creasy Visiting Professor of Clinical Pharmacology at the University of Oregon Medical School, 1981; University of Cincinnati Medical School, 1984.

Department of Biochemistry
St. Mary's Hospital Medical School
London, England

Department of Clinical Pharmacology
Karolinska Institutet
Stockholm, Sweden

Temple University
Philadelphia, Pennsylvania

U.S. Navy

Temple University
Philadelphia, Pennsylvania

Community General Hospital
Reading Pennsylvania

Temple University
Philadelphia, Pennsylvania

Cornell University
Ithaca, New York

1969-1970, Visiting Scientist with
Professor R.T. Williams

1970, Visiting Scientist with
Professor Folke Sjoqvist

1967-1971, Assistant Professor of
of Pharmacology and Internal
Medicine

1965-1967, Assistant Professor of
Pharmacology, Instructor of
Internal Medicine

1965, Instructor of Pharmacology,
Instructor of Internal Medicine

1962-1965, Instructor of
Pharmacology, Resident in Internal
Medicine

1960-1962, Senior Medical Officer
U.S. Naval Station, Trinidad

1959-1960, U.S.P.H.S.
Postdoctoral Fellowship in
Pharmacology with Dr. R. W. Sevy

1958-1959, Internship

1955-1958, Summer Student Research
Fellow in Physiology and
Pharmacology with Drs. E. A. Ohler
and R. W. Sevy

1954-1958, Medical School
(M.D., 1958)

1951-1954, Pre-medical (no degree)

Julius W. Sturmer Memorial Lecture Award of the Philadelphia College of Pharmacy and Science, 1982.

Cornell University Medical College Second Year Teaching Award, 1986, 1992.

Temple University Medical School Alumni Achievement Award, 1988.

Cornell University Medical College Alumni Association Honorary Fellowship, 1993.

The Departmental Associates of The New York Hospital-Cornell Medical Center established a program to provide minority college students with summer research opportunities and named it the Marcus M. Reidenberg Gateways to Science Program, 1993.

Pfizer Visiting Professor of Clinical Pharmacology, Meharry Medical College, 1995.

EXTRACURRICULAR ACTIVITIES

World Health Organization

Expert Advisory Panel on Drug Evaluation, Member 1989-1993, 1993-1997

Expert Committee on the Use of Essential Drugs, Rapporteur, 1989

Temporary Advisor, WHO International Drug Monitoring Program, 1990

Expert Committee on the Use of Essential Drugs, Rapporteur, 1991

Expert Committee on the Use of Essential Drugs, Rapporteur, 1993

Temporary Advisor, Special Program of Research, Development, and Research Training in Human Reproduction, 1992

Advisor about Essential Drugs Program, Ministry of Health, People's Republic of China, 1993

American College of Physicians

Chairman, Ad Hoc Committee on Clinical Pharmacology, 1971

Chairman, Committee on Clinical Pharmacology, 1972-1977

Member, MKSAP VI Committee, 1980-1982

Director, C.M.E. Course, Individualization of Drug Therapy, 1973

Director, C.M.E. Course, The Clinical Pharmacology of Symptom Control, 1982

American Society for Pharmacology and Experimental Therapeutics

Member of Executive Committee, Division of Clinical Pharmacology, 1971-1978, 1980-

Acting Chairman, Executive Committee, Division of Clinical Pharmacology, 1972

Membership Committee, 1979-1982; Chairman, 1981-1982

Educational Affairs Committee, Chairman of Subcommittee on Continuing Medical Education, 1980-1981

Program Chairman for Second World Congress on Clinical Pharmacology, Washington, D.C., July-August 1983

Nominating Committee, 1984

Member, Board of Publications Trustees, 1985-

International Union of Pharmacology

Member, Working Group on Drug Metabolism, 1982-1984
Vice Chairman, Section on Clinical Pharmacology, 1984-1987
Chairman, Section of Clinical Pharmacology, 1987-1989
Immediate Past Chairman, Section of Clinical Pharmacology, 1989-1992
Member, Working Group to Review IUPHAR Statutes, 1988
Auditor, 1990-1993
Member, International Advisory Committee, World Conference on Clinical Pharmacology of 1992
Member, International Advisory Committee, World Conference on Clinical Pharmacology of 1996
Member, Membership Committee, 1990-1993

American Society for Clinical Pharmacology and Therapeutics

Board of Directors, 1975-1977, 1979-1982, 1986-
Vice President, 1982-1983
President Elect, 1983-1984
President, 1984-1985
Multiple Committee Memberships, 1980-

Consultant, South-to-South Cooperation in Reproductive Health, 1991-

Chairman, Session on Clinical Pharmacokinetics, Gordon Research Conference on Drug Metabolism, 1971 and 1976

Consultant to Drug Research Board, National Academy of Sciences-National Research Council, 1968-1970

Food and Drug Administration

Consultant, 1971
Member, Project Advisory Group, Experiment in Early Postmarketing Surveillance of Drugs, 1977-1982
Invited Expert, Fertility and Maternal Health Drugs Advisory Committee, 1990
Member, Over-The-Counter (OTC) Drugs Advisory Committee, 1992-1995.

Consultant, Walter Reed Army Medical Center, 1974-1977

National Institutes of Health

Special Study Section, 1980 and 1986
Task Force on Geriatric Medicine, 1980
Pharmacological Sciences Review Committee (Study Section), 1980-1985
Workshop Chairman, Program Initiatives in Gerontological Pharmacology 1981
Consensus Conference on Pain Management Panel Member, 1986
Epidemiology and Disease Control Special Study Section, 1990
Data Safety Monitoring Review Committee for MIRA trial, 1991-1993

Joint Commission on Prescription Drug Use, Member, 1976; Vice Chairman, 1977-1980

Consultant, Hoffmann-La Roche, Inc., 1975-

Consultant, Genta, Inc. 1994-

Association of American Medical Colleges Ad Hoc Committee on AAMC/FDA
Interactions, 1978-1982

Merck Company Foundation
International Clinical Pharmacology Fellowship Awards Selection Committee
1992-1995, Chairman 1994

American Federation for Aging Research
Research Committee 1986-1992
Fellowship Selection Committee 1993, 1994

Award Committee for Nellie Westerman Prize for Research in Ethics of the
American Federation for Clinical Research, 1975-1978

USP - Delegate from Cornell University Medical College, 1975-1980
Advisory Panel on Geriatrics, Committee on Revision, 1980-1990

Consultant, Office of Technology Assessment, Congress of the United States,
1981

Consultant, New York State Department of Health, 1988-1992

Research Committee, American Federation for Aging Research, 1986-1992

Vice Chairman, Greater Philadelphia Committee for Medical-Pharmaceutical
Sciences, 1968-1974

Representative of Pennsylvania Medical Society to Task Force on Drug Handling
of the Commonwealth of Pennsylvania, 1968

UNICEF
Emergency Operations in former Yugoslavia, Advisor for Manual for Essential
Drugs, 1994

USP DI-AMA DE Advisory Council, 1995-

SCIENTIFIC PUBLICATIONS

Associate Editor, Clinical Pharmacology and Therapeutics, 1980-1984
Editor, Clinical Pharmacology and Therapeutics, 1985-

EDITORIAL BOARDS

Primary Care, 1974-1979
Journal of Dialysis, 1976-1985
Clinical Pharmacokinetics, 1976-
Archives Internationales de Pharmacodynamie et de Therapie, 1976-
Pharmacology, 1978-1985
Clinical Pharmacology and Therapeutics, 1978-1980
Rational Drug Therapy, 1978-1985
Renal Physiology, 1978-1985
Therapeutic Drug Monitoring, 1978-
Trends in Pharmacological Sciences, 1978-
Clinical Nephrology, 1978-

BOOKS

Reidenberg, M.M.: Renal Function and Drug Action. Philadelphia, PA, W.B. Saunders Co., 1971.

Reidenberg, M.M., editor: Individualization of Drug Therapy. Medical Clinics of North America, Philadelphia, PA, W.B. Saunders Co., September, 1974.

Rubin, A.L., Stenzel, K.H., and Reidenberg, M.M., editors: Symposium on Drug Action and Metabolism in Renal Failure. Amer. J. Med., 62:459-563, 1977.

Reidenberg, M.M., editor: The Clinical Pharmacology of Symptom Control. Medical Clinics of North America, Philadelphia, PA, W.B. Saunders Co., September, 1982.

Lemberger, L. and Reidenberg, M.M., editors: Proceedings of Second World Conference on Clinical Pharmacology and Therapeutics. American Society for Pharmacology and Therapeutics, Bethesda, MD, 1984.

Reidenberg, M.M. and Erill, S., editors: Drug-Protein Binding. Praeger, New York, NY, 1986.

Reidenberg, M.M., editor: The Clinical Pharmacology of Biotechnology Products. Excerpta Medica, New York, NY, 1991.

Publications

Original Research in Refereed Journals

1. Hartman, J.D. and Reidenberg, M.M.: Comparison of the glycolytic activity of blood and exudate leucocytes. J. Appl. Physiol., 12:477-481, 1958.

2. Reidenberg, M.M., Ohler, E.A., and Sevy, R.W.: Cardiovascular responses to norepinephrine in acute adrenal insufficiency. *Proc. Soc. Exper. Biol. and Med.*, 97:889-892, 1958.
3. Soloff, L.A., Reidenberg, M.M., Winters, W.L. Jr., and Bello, C.T.: Clinical experiences with bretylium tosylate. *Ann. N.Y. Acad. Sci.*, 88(4):1003-1010, 1960.
4. Reidenberg, M.M. and Sevy, R.W.: Effect of adrenocortical steroids on bone electrolyte metabolism. *Proc. Soc. Exper. Biol. and Med.*, 107:132-134, 1961.
5. Reidenberg, M.M., Ohler, E.A., Sevy, R.W., and Harakal, C.: Hemodynamic changes in adrenalectomized dogs. *Endocr.*, 72:918-923, 1963.
6. Reidenberg, M.M. and Barry, W.E.: Low molecular weight dextran. *Lancet*, 1:988-989, 1964.
7. Adler, M.W., Reidenberg, M.M., Harakal, C., Rusq, B.F., and Papacostas, C.A.: Cardiovascular effects of hexafluorodiethyl ether. *Int. J. Neuropsychiatry*, 1:511-512, 1965.
8. Harakal, C., Reidenberg, M.M., Sevy, R.W., and Ohler, E.A.: Hemodynamic effects of adrenal medullectomy in the dog. *Am. J. Physiol.*, 210:5-6, 1966.
9. Reidenberg, M.M., Haag, B.L., Channick, B.J., Shuman, C.R., and Wilson, G.G.: The response of bone to metabolic acidosis in man. *Metabolism*, 15:236-241, 1966.
10. Molthan, L., Reidenberg, M.M., and Eichman, M.F.: Positive direct Coombs' tests due to cephalothin. *New Engl. J. Med.*, 277:123-125, 1967.
11. Barrera, F., Reidenberg, M.M., and Winters, W.L.: Pulmonary function in obese patients. *Am. J. Med. Sci.*, 254:785-796, 1967.
12. Haag, B.L., Reidenberg, M.M., Shuman, C.R., and Channick, B.J.: Aldosterone, 17-ketosteroid, and fluid and electrolyte responses to starvation and selective refeeding. *Am. J. Med. Sci.*, 254:652-658, 1967.
13. Reidenberg, M.M.: Registry of adverse drug reactions. Report of the drug reaction registry subcommittee of The Greater Philadelphia Committee for Medical-Pharmaceutical Sciences. *J.A.M.A.*, 203:31-43, 1968.
14. Reidenberg, M.M., Sevy, R.W., and Cucinotta, A.J.: Hypercalciuria during acidosis in hypoparathyroidism. *Proc. Soc. Exper. Biol. and Med.*, 127:1-3, 1968.
15. Harakal, C., Sevy, R.W., Reidenberg, M.M., and Faust, R.E.: Effect of adrenal medullectomy and total adrenalectomy on the hemodynamic responses to tyramine. *J. Pharmacol. Exper. Ther.*, 160:292-299, 1968.

16. Reidenberg, M.M. and Lowenthal, D.T.: Adverse nondrug reactions. *New Engl. J. Med.*, 279:678-679, 1968.
17. Reidenberg, M.M., Kostenbauder, H., and Adams, W.P.: The rate of drug metabolism in obese volunteers before and during starvation and in azotemic patients. *Metabolism*, 18:209-213, 1969.
18. Barrera, E.F., Reidenberg, M.M., Winters, W.L., and Hungspreugs, S.: Ventilation perfusion relationships in the obese patient. *J. Appl. Physiol.*, 26:420-426, 1969.
19. Magargal, L.E., Magargal, H., and Reidenberg, M.M.: Effect of steroid hormones on the parathyroid hormone dose-response curve. *J. Pharmacol. and Exper. Ther.*, 169(1):138-141, 1969.
20. Coleman, E.H. and Reidenberg, M.M.: Effect of thyroparathyroidectomy on skeletal sodium in the rat. *Endocrinology*, 85:175-176, 1969.
21. Glauser, S.C., Glauser, E.M., Reidenberg, M.M., Rusy, B.F., and Tallarida, R.J.: Metabolic changes associated with the cessation of cigarette smoking. *Arch. Environ. Health*, 20:377-381, March, 1970.
22. Reidenberg, M.M., Odar-Cederlof, I., Von Bahr, C., Borga, O., Sjoqvist, F.: Protein binding of diphenylhydantoin and desmethylinipramine in plasma from patients with poor renal function. *New Engl. J. Med.*, 285:264-267, 1971.
23. Lowenthal, D.T. and Reidenberg, M.M.: The heart rate response to atropine in uremic patients, obese subjects before and during fasting, and patients with other chronic illnesses. *Proc. Soc. Exper. Biol. and Med.*, 139(2):390-393, 1972.
24. Reidenberg, M.M., James, M., and Dring, L.G.: The rate of procaine hydrolysis in serum from normal subjects and diseased patients. *Clin. Pharmacol. and Ther.*, 13:279-284, 1972.
25. James, M., Smith, R.L., Williams, R.T., and Reidenberg, M.M.: The conjugation of phenylacetic acid in man, subhuman primates, and some non-primate species. *Proceedings of The Royal Society B*, 182:25-35, 1972.
26. Reidenberg, M.M.: The procaine esterase activity of serum from different mammalian species. *Proc. Soc. Exper. Biol. and Med.*, 140:1059-1061, 1972.
27. Drayer, D.E. and Reidenberg, M.M.: Metabolism of tetralin and toxicity of Cuprex^(R) in man. *Drug Metabolism and Disposition*, 1:577-579, 1973.
28. Lowenthal, D.T., Chardo, F., and Reidenberg, M.M.: Removal of mercury by peritoneal dialysis. *Arch. Int. Med.*, 134:139-141, 1974.
29. Reidenberg, M.M., Drayer, D.E., DeMarco, A.L., and Bello, C.T.:

Hydralazine elimination in man. Clin. Pharmacol. and Ther., 14:970-977, 1973.

30. Reidenberg, M.M., Shear, L., and Cohen, R.V.: Elimination of isoniazid in patients with impaired renal function. Am. Review of Respir. Dis., 108:1426-1428, 1973.
31. Reidenberg, M.M. and Martin, J.H.: The acetylator phenotype of patients with systemic lupus erythematosus. Drug Metabolism and Disposition, 2:71-73, 1974.
32. Kessler, K.M., Lowenthal, D.T., Warner, H., Gibson, T., Briggs, W., and Reidenberg, M.M.: Quinidine elimination in patients with congestive heart failure or poor renal function. New Engl. J. Med., 290:706-709, 1974.
33. Drayer, D.E., Reidenberg, M.M., and Sevy, R.W.: N-acetylprocainamide: An active metabolite of procainamide. Proc. Soc. Exper. Biol. and Med., 146:358-363, 1974.
34. Drayer, D.E., Strong, J.M., Jones, B., Sandler, A., and Reidenberg, M.: In vitro acetylation of drugs by human blood cells. Drug Metabolism and Distribution, 2:499-505, 1974.
35. Affrime, M. and Reidenberg, M.M.: The protein binding of some drugs in plasma from patients with alcoholic liver disease. Eur. J. Clin. Pharmacol., 8:267-269, 1975.
36. Reidenberg, M.M., Drayer, D.E., Levy, M., and Warner, H.: The polymorphic acetylation of procainamide by man. Clin. Pharmacol. Ther., 17:722-730, 1975.
37. Reidenberg, M.M. and Vesell, E.S.: Unaltered metabolism of antipyrine and tolbutamide during fasting in man. Clin. Pharmacol. Ther., 17:650-656, 1975.
38. Reidenberg, M.M. and Caccese, R.W.: Lymphocyte transformation tests and suspected drug allergy. J. Lab. Clin. Med., 86:997-1002, 1975.
39. Cerletti, C., Keinath, S.H., Reidenberg, M.M., and Adler, M.: Relationship between method of morphine administration, plasma levels, and the withdrawal syndrome in rats. Pharmacol., Biochem., and Behavior, 4:323-327, 1976.
40. Bagwell, E.E., Walle, T., Drayer, D.E., Reidenberg, M.M., Pruett, J.K.: Correlation of the electrophysiological and antiarrhythmic properties of the N-acetyl metabolite of procainamide with plasma and tissue drug concentrations in the dog. J. Pharmacol. Exper. Ther., 197:38-48, 1976.

41. White, R.P., Sealey, J., Reidenberg, M.M., Stenzel, K.H., Sullivan, J.F., David, D.S., Laragh, J.H., and Rubin, A.L.: Mechanisms of blood pressure control in anephrics: plasma renin and dopamine B hydroxylase activity. *Trans. Amer. Soc. Artif. Int. Organs*, 22:420-423, 1976.
42. Chami, J., Reidenberg, M., Wellner, D., David, D.S., Rubin, A., and Stenzel, K.H.: Essential amino acid metabolism in maintenance dialysis patients. *Trans. Amer. Soc. Artif. Int. Organs*, 22:168-173, 1976.
43. Reidenberg, M.M., Lowenthal, D.T., Briggs, W., and Gasparo, M.: Pentobarbital elimination in patients with poor renal function. *Clin. Pharmacol. Ther.*, 20:67-71, 1976.
44. Drayer, D.E., Cordova, M., Slaven, B.H., Bagwell, E.E., and Reidenberg, M.M.: The antiarrhythmic activity of p-hydroxy-N-(2-diethylaminoethyl) benzamide (the p-hydroxy isostere of procainamide) in dogs and mice. *J. Med. Chem.*, 20:270-274, 1977.
45. Tapia, L., Cheigh, J.S., David, D.S., Sullivan, J.F., Saal, S., Reidenberg, M.M., Stenzel, K.H., and Rubin, A.L.: Treatment of pruritus in dialysis patients with parenteral lidocaine. *New Engl. J. Med.*, 296:261-262, 1977.
46. Szeto, H.H., Inturrisi, C.E., Houde, R., Saal, S., Cheigh, J., Reidenberg, M.M.: Accumulation of normeperidine, an active metabolite of meperidine, in patients with renal failure or cancer. *Ann. Int. Med.*, 86:738-741, 1977.
47. Drayer, D.E., Lowenthal, D.T., Woosley, R.L., Nies, A.S., Schwartz, A., and Reidenberg, M.M.: Cumulation of N-acetylprocainamide, an active metabolite of procainamide, in patients with impaired renal function. *Clin. Pharmacol. Ther.*, 22:63-69, 1977.
48. Saudek, C.D., Werns, S., and Reidenberg, M.M.: Phenytoin in the treatment of diabetic symmetrical polyneuropathy. *Clin. Pharmacol. Ther.*, 22:196-199, 1977.
49. Drayer, D.E., Restivo, K., and Reidenberg, M.M.: Specific determination of quinidine and (3S)-3-hydroxyquinidine in human serum by high pressure liquid chromatography. *J. Lab. Clin. Med.*, 90:816-822, 1977.
50. Romankiewicz, J.A., Reidenberg, M.M., Drayer, D.E., and Franklin, J.E.: The noninterference of aluminum hydroxide gel with quinidine sulfate absorption: An approach to control quinidine induced diarrhea. *Amer. Heart J.*, 96:518-521, 1978.
51. Reidenberg, M.M., Levy, M., Warner, H., Coutinho, C.B., Schwartz, M.A., Yu, G., and Cheripko, J.: Relationship between diazepam dose, plasma level, age, and central nervous system depression. *Clin. Pharmacol. Ther.*, 23:371-374, 1978.

52. Drayer, D.E., Lowenthal, D.T., Restivo, K.M., Schwartz, A., Cook, C.E., and Reidenberg, M.M.: Steady state serum levels of quinidine and active quinidine metabolites in cardiac patients with varying degrees of renal function. *Clin. Pharmacol. Ther.*, 24:31-39, 1978.
53. Woosley, R.L., Drayer, D.E., Reidenberg, M.M., Nies, A.S., Carr, K., and Oates, J.A.: Effect of acetylator phenotype on the rate at which procainamide induces antinuclear antibodies and the lupus syndrome. *New Engl. J. Med.*, 298:1157-1159, 1978.
54. Dietrich, J., Krauss, A.N., Reidenberg, M.M., Drayer, D.E., and Auld, P.A.M.: Alterations in state in apneic pre-term infants receiving theophylline. *Clin. Pharmacol. Ther.*, 24:474-478, 1978.
55. Jones, B.R., Baran, A., and Reidenberg, M.M.: Evaluating patients' warfarin requirements. *J. Amer. Geriatrics Soc.*, 28:10-12, 1980.
56. Meyers, T.F., Milsap, R.L., Krauss, A.N., Auld, P.A.M., and Reidenberg, M.M.: Low dose theophylline therapy in idiopathic apnea of prematurity. *J. Ped.*, 96:99-103, 1980.
57. Lahita, R., Kluger, J., Drayer, D.E., Koffler, D., and Reidenberg, M.M.: Antibodies to nuclear antigens in patients treated with procainamide or acetylprocainamide. *New Engl. J. Med.*, 301:1382-1385, 1979.
58. Drayer, D.E., Hughes, M., Lorenzo, B., and Reidenberg, M.M.: The prevalence of high (3S)-3-hydroxyquinidine/quinidine ratios in serum and the clearance of quinidine in cardiac patients of varying ages. *Clin. Pharmacol. Ther.*, 27:72-75, 1980.
59. Jones, B.R., Bhalla, R.B., Mladek, J., Kaleya, R.N., Gralla, R.J., Alcock, N.W., Schwartz, M.K., Young, C.W., and Reidenberg, M.M.: Comparison of methods of evaluating nephrotoxicity of cis-platinum. *Clin. Pharmacol. Ther.*, 27:557-562, 1980.
60. Kluger, J., Drayer, D., Reidenberg, M.M., Ellis, G., Lloyd, V., Tyberg, T., and Hayes, J.: The clinical pharmacology and antiarrhythmic efficacy of acetylprocainamide in patients with arrhythmias. *Amer. J. Cardiol.*, 45:1250-1257, 1980.
61. Merle, L.J., Reidenberg, M.M., Camacho, M.T., Jones, B.R., and Drayer, D.E.: Renal injury in patients with rheumatoid arthritis treated with gold. *Clin. Pharmacol. Ther.*, 28:216-222, 1980.
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